

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

FILED

MAY 11 2022

Clerk, U. S. District Court
Eastern District of Tennessee
At Knoxville

IN THE MATTER OF THE
ADMINISTRATIVE INSPECTION OF:

SMOKY MOUNTAIN PHARMACY
958 Dolly Parton Parkway
Sevierville, Tennessee 37862

Magistrate No. 3:22-mj-1124

APPLICATION AND AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF SEVIER, to-wit:

I, Merry C. Church, being first duly sworn, do hereby depose and state as follows:

Your affiant, Merry C. Church, is a duly appointed Diversion Investigator of the Drug Enforcement Administration, United States Department of Justice, assigned to the Knoxville, Tennessee District Office.

Pursuant to Title 21, United States Code (U.S.C.), Sections 878(2) and 880(b)(1), (2), and (3), and Section 3, Appendix to Subpart R. Title 28, Code of Federal Regulations (C.F.R.), your affiant is authorized to execute administrative inspection warrants for the purpose of inspecting controlled premises of persons and firms registered under the Controlled Substances Act (CSA) (21 U.S.C. § 800 *et seq.*) in order to inspect, copy and verify the correctness of all records, reports and other documents required to be kept or made under 21 U.S.C. § 827 and 21 C.F.R. § 1304.01 *et seq.*

Smoky Mountain Pharmacy is registered under the provisions of the CSA, 21 U.S.C. § 823 *et seq.*, as a Retail Pharmacy, and has been assigned DEA registration number BS8484925 in Schedules 2, 2N, 3, 3N, 4, and 5. The registered address for Smoky Mountain Pharmacy is 958 Dolly Parton Parkway, Sevierville, Tennessee 37862 and described as a retail pharmacy located in a single-story strip mall building. The office itself displays the name "SMOKY MOUNTAIN COMPOUND PHARMACY," above the entrance. That said place of business is a controlled premise within the meaning of 21 U.S.C. § 880(a) and 21 C.F.R. § 1316.02(c).

Smoky Mountain Pharmacy is required to keep complete and accurate records, for at least two (2) years, of all controlled substances received, sold, delivered or otherwise disposed of by

it pursuant to 21 U.S.C. § 827 and 21 CFR § 1304.01 *et seq.* on the controlled premises. Pursuant to 21 CFR § 1304.22(c), persons registered to dispense controlled substances are required to record the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed the substance.

On February 17, 2021, George E. Miller, owner and pharmacist-in-charge (PIC) of Smoky Mountain Pharmacy, submitted a DEA form 224a Renewal Application for DEA Registration, to renew DEA registration number BS8484925. This application requires the applicant to answer questions regarding liabilities of the applicant. One such question asks, *“Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?”* Another question asks, *“If the applicant is a corporation, association, partnership, or pharmacy, has any officer, partner, stockholder, or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law...or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation, or is any such action pending?”*

In response to these questions, Mr. Miller disclosed that his Tennessee pharmacist license was placed on probation for five years, from 2008 through 2013, for filling prescriptions without proper authorization by the providers. However, Mr. Miller failed to disclose the following liabilities:

- In 2018, the Kentucky Board of Pharmacy permanently revoked Mr. Miller’s Kentucky pharmacist license after Mr. Miller failed to complete all required continuing education credits, failed to respond to the Kentucky Board of Pharmacy’s attempts to enter into an Agreed order, and failed to participate in a hearing regarding Mr. Miller’s Kentucky pharmacist license. Your affiant knows of this disciplinary action by her review of documents obtained from the Kentucky Board of Pharmacy.
- In 2020, the Tennessee Board of Pharmacy placed Mr. Miller’s Tennessee pharmacist license under probation for one year for due to violations of Tennessee’s Food, Drug, and Cosmetic Act. The violations involved maintaining expired drugs, to include controlled substances, without quarantining those drugs; compounding drugs from returned drugs and dispensing the compounded drugs to a feline patient; and falsifying critical information to the Board’s inspector about producing sterile compounds, amongst other violations. Your affiant knows of this disciplinary action by her review of documents obtained from the official website for the Tennessee Department of Health.

Your affiant notes that, pursuant to 21 USC § 824(a)(1), material falsification of any application to DEA is a grounds to deny or revoke a DEA registration.

On August 27, 2021, and in furtherance of a separate investigation involving complaints against a local physician, investigators from the Knoxville District Office of the DEA reviewed prescriptions at Smoky Mountain Pharmacy. In the course of their review, investigators noted the following irregularities:

- Two prescriptions did not include the date that the prescriptions were written.
- Four prescriptions did not identify the dosage form.
- Three prescriptions did not include the prescriber's DEA registration number and address.

Your affiant attests that these irregularities are all potential violations of 21 C.F.R. § 1306.05(a), which states, "All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner."

Investigators further noted one prescription, dated July 29, 2021, that authorized the dispensing of two Subutex 8mg tablets. Instructions on the prescription prohibited the prescription from being filled until August 12, 2021. However, dispensing information on the prescription indicated that Smoky Mountain Pharmacy dispensed four tablets on August 5, 2021. Investigators last noted the existence of several prescriptions that, despite bearing the names and DEA registration numbers of two separate physicians, appeared to contain the same authorizing signature.

Your affiant represents that Smoky Mountain Pharmacy, and Pharmacist George M. Miller, are under investigation by the Drug Enforcement Administration for a failure to disclose all liabilities upon renewal of DEA registration BS8484925, in violation of 21 U.S.C. § 843(a)(4)(A). Your affiant denotes that Smoky Mountain Pharmacy and Pharmacist George M. Miller, are under investigation by the Drug Enforcement Administration for failure to keep a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him, in violation of 21 C.F.R. 1304.21(a).

Your affiant further represents that the need for further inspecting Smoky Mountain Pharmacy's registered location of 958 Dolly Parton Parkway, Sevierville, Tennessee 37862, and the need for verifying the correctness of inventories, records, reports, and other documents required to be kept under the CSA, result from a valid public interest in the effective enforcement of the CSA and implementing regulations.

Furthermore, your affiant has examined files and records of the Drug Enforcement Administration (DEA) and has determined that Smoky Mountain Pharmacy has never been inspected by the DEA. "Probable Cause" in the traditional criminal law sense is not required to support the issuance of an administrative warrant. Marshall v. Barlow's Inc., 436 U.S. 307, 320 (1978); *see also* United States v. Acklen, 690 F.2d 70, 72-73 (6th Cir. 1982). Indeed, the fact that a registrant has never been inspected to insure compliance with compulsory record keeping requirements, is a circumstance that alone is sufficient to justify an administrative warrant. United States v. Voorhies, 663 F.2d 30, 33 (6th Cir. 1981) United States v. Goldfine, 538 F.2d 815, 818-819 (9th Cir. 1976); United States v. Prendergast, 585 F.2d 69, 70 (3rd Cir. 1978).

The affiant further states that the inspection will be conducted within regular business hours, and that the Investigator's credentials will be presented to the registrant, and that the inspection will begin as soon as practicable after the issuance of the warrant and will be completed with reasonable promptness and that the warrant will be returned within 10 days.

The affiant further states that the inspection will extend to the inspection and copying of inventories, records, reports, prescriptions, order forms, invoices, and other documents, including electronically-stored data, required to be kept and the inspection of all other things therein including records, files, and papers appropriate for the verification of the records, reports, and documents required to be kept under the CSA. The inspection will also extend to the inspection and inventory of stocks of controlled substances, finished or unfinished substances and pertinent equipment associated with the storage and handling of controlled substances, and if necessary and applicable, records and/or samples of controlled substances will be seized.

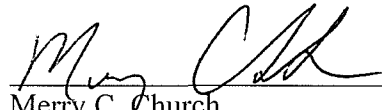
Based on information obtained by DEA investigators, from Tennessee Board of Pharmacy investigators who have conducted inspections at Smoky Mountain Pharmacy, the pharmacy utilizes an electronic record-keeping system as the primary record for dispensing controlled substances. Henceforth, the affiant requests that this Court authorize investigators and agents to copy, or "mirror image" all computerized storage areas, including hard drives, diskettes, and other such storage devices where records and documents sought by this administrative inspection warrant may be found in electronic form and perform whatever techniques are necessary to ensure that the imaged copies are accurate copies. As to inspection of the contents, investigators or agents are requesting authorization to analyze the electronically stored data using any of the following techniques: (a) surveying various file "directories" and the individual files they contain in order to locate records authorized for inspection or seizure by the warrant; (b) "opening" or reading the first few "pages" of such files in order to determine their precise contents; (c) "scanning" storage areas to discover and possibly recover recently deleted data and scanning storage areas for deliberately hidden files; and (d) performing electronic "keyword" searches through all electronic storage areas to determine whether occurrences of language contained in such storage areas exist that are intimately related to the subject matter of the inspection.

Although the Act does not explicitly provide for copying of items listed under 21 U.S.C. 880(b)(3)(B), the affiant requests that the court authorize the copying of (and if necessary, seizure for the purpose of copying) such items (whether they be in written or printed form) in order to appropriately verify the records that are required to be kept under 21 U.S.C. 880(b)(3)(A). Further, if the relevant items are seized, copied, and returned in a reasonably prompt fashion, it will allow DEA to more quickly, efficiently, and thoroughly inspect the registered premises, and minimize disruption of pharmacy operations.

The affiant will be accompanied by one or more Investigators who are employees of the Attorney General authorized to conduct administrative inspections. If the registrant or any person subject to the Act refuses to permit execution of the administrative inspection warrant, or impedes an Investigator in the execution of that warrant, he or she will be advised that such refusal or action constitutes a violation of section 402(a)(6) of the Act (21 U.S.C. 842(a)(6)). If he or she persists and the circumstances warrant, he or she shall be arrested and the inspection shall commence or continue.

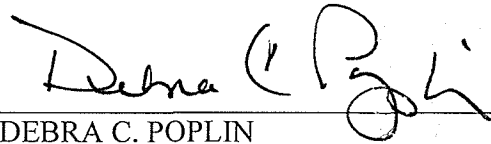
A return will be made to this United States Magistrate Judge upon the completion of the inspection. The affiant further states that she has verified and has knowledge of the facts alleged in this affidavit, and that they are true to the best of her knowledge.

Further your affiant sayeth naught.



Merry C. Church
Diversion Investigator
Drug Enforcement Administration

Sworn to before me and subscribed in my presence on this 3rd day of May, 2022.



DEBRA C. POPLIN
United States Magistrate Judge